§485.918

CMHC to assess processes of care, CMHC services, and operations.

- (b) Standard: Program data. (1) The program must use quality indicator data, including client care, and other relevant data, in the design of its program.
- (2) The CMHC must use the data collected to do the following:
- (i) Monitor the effectiveness and safety of services and quality of care.
- (ii) Identify opportunities and priorities for improvement.
- (3) The frequency and detail of the data collection must be approved by the CMHC's governing body.
- (c) Standard: Program activities. (1) The CMHC's performance improvement activities must:
- (i) Focus on high risk, high volume, or problem-prone areas.
- (ii) Consider incidence, prevalence, and severity of problems.
- (iii) Give priority to improvements that affect behavioral outcomes, client safety, and person-centered quality of care.
- (2) Performance improvement activities must track adverse client events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the CMHC.
- (3) The CMHC must take actions aimed at performance improvement and, after implementing those actions, the CMHC must measure its success and track performance to ensure that improvements are sustained.
- (d) Standard: Performance improvement projects. CMHCs must develop, implement and evaluate performance improvement projects.
- (1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the CMHC's population and internal organizational needs, must reflect the scope, complexity, and past performance of the CMHC's services and operations.
- (2) The CMHC must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

- (e) Standard: Executive responsibilities. The CMHC's governing body is responsible for ensuring the following:
- (1) That an ongoing QAPI program for quality improvement and client safety is defined, implemented, maintained, and evaluated annually.
- (2) That the CMHC-wide quality assessment and performance improvement efforts address priorities for improved quality of care and client safety, and that all improvement actions are evaluated for effectiveness.
- (3) That one or more individual(s) who are responsible for operating the QAPI program are designated.

§ 485.918 Condition of participation: Organization, governance, administration of services, and partial hospitalization services.

The CMHC must organize, manage, and administer its resources to provide CMHC services, including specialized services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health service area who have been discharged from an inpatient mental health facility.

- (a) Standard: Governing body and administrator. (1) A CMHC must have a designated governing body made up of two or more designated persons, one of which may be the administrator, that assumes full legal authority and responsibility for the management of the CMHC, the services it furnishes, its fiscal operations, and continuous quality improvement. One member of the governing body must possess knowledge and experience as a mental health clinician.
- (2) The CMHC's governing body must appoint an administrator who reports to the governing body and is responsible for the day-to-day operation of the CMHC. The administrator must be a CMHC employee and meet the education and experience requirements established by the CMHC's governing body.
- (b) Standard: Provision of services. (1) A CMHC must be primarily engaged in providing the following care and services to all clients served by the CMHC regardless of payer type, and must do so in a manner that is consistent with

the following accepted standards of practice:

- (i) Provides outpatient services, including specialized outpatient services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health service area who have been discharged from inpatient mental health facilities.
- (ii) Provides 24-hour-a-day emergency care services.
- (iii) Provides day treatment, partial hospitalization services other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.
- (iv) Provides screening for clients being considered for admission to State mental health facilities to determine the appropriateness of such services, unless otherwise directed by State law.
- (v) Provides at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act, as measured by the total number of CMHC clients treated by the CMHC for whom services are not paid for by Medicare, divided by the total number of clients treated by the CMHC for each 12-month period of enrollment.
- (A) A CMHC is required to submit to CMS a certification statement provided by an independent entity that certifies that the CMHC's client population meets the 40 percent requirement specified at this paragraph (b)(1)(v).
- (B) The certification statement described in paragraph (b)(1)(v)(A) of this section is required upon initial application to enroll in Medicare, and as a part of revalidation, including any off cycle revalidation, thereafter carried out pursuant to $\S424.530$ of this chapter. Medicare enrollment will be denied or revoked in instances where the CMHC fails to provide the certification statement as required. Medicare enrollment will also be denied or revoked if the 40 percent requirement as specified in this paragraph (b)(1)(v) is not met.
- (vi) Provides individual and group psychotherapy utilizing a psychiatrist, psychologist, or other licensed mental health counselor, to the extent authorized under State law.
 - (vii) Provides physician services.

- (viii) Provides psychiatric nursing services.
- (ix) Provides clinical social work services.
- (x) Provides family counseling services, with the primary purpose of treating the individual's condition.
- (xi) Provides occupational therapy services.
- (xii) Provides services of other staff trained to work with psychiatric clients.
- (xiii) Provides drugs and biologicals furnished for therapeutic purposes that cannot be self-administered.
- (xiv) Provides client training and education as related to the individual's care and active treatment.
- (xv) Provides individualized therapeutic activity services that are not primarily recreational or diversionary.
 - (xvi) Provides diagnostic services.
- (2) The CMHC and individuals furnishing services on its behalf must meet applicable State licensing and certification requirements.
- (c) Standard: Professional management responsibility. A CMHC that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management and oversight of staff and services for all arranged services. As part of retaining financial management responsibility, the CMHC must retain all payment responsibility for services furnished under arrangement on its behalf. Arranged services must be supported by a written agreement which requires that all services be as follows:
 - (1) Authorized by the CMHC.
- (2) Furnished in a safe and effective manner.
- (3) Delivered in accordance with established professional standards, the policies of the CMHC, and the client's active treatment plan.
- (d) Standard: Staff training. (1) A CMHC must provide education about CMHC care and services, and personcentered care to all employees, volunteers, and staff under contract who have contact with clients and their families.

Pt. 486

- (2) A CMHC must provide an initial orientation for each individual furnishing services that addresses the specific duties of his or her job.
- (3) A CMHC must assess the skills and competence of all individuals furnishing care and, as necessary, provide in-service training and education programs where indicated. The CMHC must have written policies and procedures describing its method(s) of assessing competency and must maintain a written description of the in-service training provided during the previous 12 months.
- (e) Standard: Physical environment—(1) Environmental conditions. The CMHC must provide a safe, functional, sanitary, and comfortable environment for clients and staff that is conducive to the provision of services that are identified in paragraph (b) of this section.
- (2) Building. The CMHC services must be provided in a location that meets Federal, State, and local health and safety standards and State health care occupancy regulations.
- (3) Infection control. There must be policies, procedures, and monitoring for the prevention, control, and investigation of infection and communicable diseases with the goal of avoiding sources and transmission of infection.
- (4) Therapy sessions. The CMHC must ensure that individual or group therapy sessions are conducted in a manner that maintains client privacy and ensures client dignity.
- (f) Standard: Partial hospitalization services. A CMHC providing partial hospitalization services must—
- (1) Provide services as defined in §410.2 of this chapter.
- (2) Provide the services and meet the requirements specified in §410.43 of this chapter.
- (3) Meet the requirements for coverage as described in §410.110 of this chapter.
- (4) Meet the content of certification and plan of treatment requirements as described in § 424.24(e) of this chapter.
- (g) Standard: Compliance with Federal, State, and local laws and regulations related to the health and safety of clients. The CMHC and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the

health and safety of clients. If State or local law provides for licensing of CMHCs, the CMHC must be licensed. The CMHC staff must follow the CMHC's policies and procedures.

PART 486—CONDITIONS FOR COV-ERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

Subpart A—General Provisions

Sec.

486.1 Basis and scope.

Subpart B [Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

- 486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.
- 486.102 Condition for coverage: Supervision by a qualified physician.
- 486.104 Condition for coverage: Qualifications, orientation, and health of technical personnel.
- 486.106 Condition for coverage: Referral for service and preservation of records.
- 486.108 Condition for coverage: Safety standards.
- 486.110 Condition for coverage: Inspection of equipment.

Subparts D-F [Reserved]

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

486.301 Basis and scope.

486.302 Definitions.

REQUIREMENTS FOR CERTIFICATION AND DESIGNATION

486.303 Requirements for certification.

486.304 Requirements for designation.

36.306 OPO service area size designation and documentation requirements.

486.308 Designation of one OPO for each service area.

486.309 Re-certification from August 1, 2006 through July 31, 2010.

486.310 Changes in control or ownership or service area.

Re-certification and De-certification

486.312 De-certification.

486.314 Appeals.

486.316 Re-certification and competition processes.